

Date: April 30, 1992

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From: Larry Tainter, Director
Bureau of Quality Assurance

Subject: Clinical Laboratory Improvement Act (CLIA) of 1988

Final CLIA '88 regulations were published in the Federal Register on 2/28/92. These regulations extend federal authority to entities of all sizes which test human specimens for determining health status. (Previous regulations covered facilities that were involved in interstate commerce or certified to perform lab services under Medicare.)

All labs in Wisconsin are now covered by the Clinical Lab Improvement Act, except for those labs performing tests for forensic purposes, research labs not producing patient results, and National Institute of Drug Abuse (NIDA) approved drug testing labs. CLIA governs every aspect of laboratory operations, including tests performed, personnel qualifications, quality control, quality assurance, proficiency testing, patient test management and records and information systems.

The basic structure of the Final Regulations sets up three categories for laboratories. Tests are categorized as either waived, Moderate Complexity or High Complexity. Laboratories may conduct any combination of tests as long as they are certified for the highest level of complexity for the tests conducted. Standards are applied based on the actual category of the test being conducted, not in accordance with the certification level of the laboratory. A laboratory may qualify for a Certificate of waiver if it restricts its testing and examinations to tests categorized as Waived Tests in the Final Regulations or added to the list by the Health Care Financing Administration (HCFA) in the future.

Laboratories conducting all other tests, i.e., Moderate and/or High Complexity Tests must obtain either a Certificate or a Certificate of Accreditation. A Registration Certificate must be obtained before applying for either a Certificate or a Certificate of Accreditation. During the Registration Certificate period, HCFA will confirm that the laboratory meets all requirements for the issuance of a Certificate or a Certificate of Accreditation. HCFA expects to implement the accreditation aspect over the next year but there are no accredited laboratory programs at this time.

What Labs Need to do First – Apply for a certificate and pay the fee. HCFA mailed a survey in November, 1991, to 600,000 entities nationwide that are potentially subject to CLIA requirements. If you returned the survey to HCFA by January 29, 1992, you will receive a preprinted application by May, 1992. You will be asked to verify the information on the application form, make any necessary changes and return the form to HCFA with the appropriate fee within 30 days of receipt of the preprinted application. The application will allow labs to apply for either a certificate of waiver, indicating that they do no more than the eight tests permitted within this lab level, or for a registration certificate. If you received a form, but did not return it, you can still send it to HCFA. If your lab did not receive a preprinted form, it is the lab's responsibility to contact HCFA to obtain an application form.

If your lab does not have an application form, contact:

Region V Health Care Financing Administration Office
105 West Adams Street, 15th Floor
Chicago, IL 60603-6201
(312) 353-9804

Labs must have an appropriate certificate by September 1, 1992. Each certificate will have a 10 digit CLIA identification number. The CLIA number will be needed when billing Medicare or Medicaid for laboratory services. Any lab without a CLIA number after 9/1/92 will not be paid for lab services.

The Wisconsin Division of Health will be responsible for all survey and subsequent certification activities for clinical labs and will begin conducting surveys under these regulations 9/1/92. All laboratories, including those with a certificate of waiver, must agree to submit to unannounced inspections at any time in order for the survey agency to assess compliance.

For copies of the 2/28/92 Federal Register, send in your request to:

Government Printing Office
Attn: New Order
P.O. Box 371954
Pittsburgh, PA 15250-7954

Specify the date of issue (2/28/92) and stock # 069-001-00042-4. Payment of \$3.50 may be made by check payable to the Superintendent of Documents or enclose your Visa or Master Card number and expiration date. Credit card orders may also be placed by calling (202) 783-3238 or by faxing/(202) 512-2250.

For additional information about the Clinical Lab Improvement Act, please call the CLIA Inquiry hotline operated by the Health Care Financing Administration at (410) 290-5850.

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cc:

-BQC Staff	-WI Assn. of Nursing Homes
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-Ann Haney, DOH Admin.	-Admin., Div. of Care and Treatment Facilities
-Kevin Piper, BHCF Dir.	-Hospice Organization of WI
-HCFA, Region V	-LTC BQC Memo Subscribers
-Illinois State Agency	-Non-LTC BQC Memo Subscribers
-Ohio State Agency	-Secy, Dept. of Reg. & Licensing
-Michigan State Agency	-Director, Bureau of Aging DCS
-Indiana State Agency	-WI Hospital Association
-Minnesota State Agency	-Bur. Long Term Support, DCS
-WI Coalition for Advocacy	-WI Homecare Organization
-Service Employees Intern. Union	-Bur. of Design, Prof., DRL
-WI Counties Assn.	-Bd. on Aging & Long Term Care
-WI Medical Records Assn. Cons. Comm.	-WI Assn. of Hospital SW and Discharge
-WI Assoc. of Homes and Services for Aging	Planners
-Comm. on Aging, Ext. Care Fac./HH (SMS)	